K002506

SMITHS INDUSTRIES
Medical Systems

H: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

SIMS Portex Inc.
10 Bowman Drive
PO Box 0724
Keene NH 03431 USA
Telephone: 603-352-3812
Fax: 603-352-3703

DEC 1 4 2000

510(K) SUMMARY:

COMPANY INFORMATION:

SIMS Portex Inc
10 Bowman Drive
Keene, NH 03431
(603) 352-3812
Contact: Timothy J. Talcott
Director, Regulatory Compliance

PREPARATION DATE OF SUMMARY:

August 11, 2000

TRADE NAME:

Breathing Filter for Disposable Anesthesia Breathing Circuits

COMMON NAME:

Breathing Circuit Bacterial Filter

PRODUCT CLASS/CLASSIFICATION:

Class II, 73 CAH, 21 CFR 868.5260

PREDICATE DEVICE(S):

SIMS Portex Inc. Breathing Filter, catalog number 002832, K830618;

DESCRIPTION:

The SIMS breathing filter for disposable anesthesia breathing circuits is a bi-directional breathing device used to reduce the transmission of microorganisms in gases delivered to and exhaled from patients and breathing systems. This device contains a filter media made of polypropylene housed within a transparent blue tinted shell. The filter features a 22 mm I.D. machine end and a barbed connector at the patient end for attachment to corrugated tubing.

The filter is intended for single use only and is supplied non-sterile. The filter is pre-attached at the machine end of the anesthesia circuit on either, or both, the expiratory or inspiratory limbs.

INDICATIONS FOR USE:

To be used with anesthesia breathing circuits where filtration of inspired and/or expired gases is required.

TECHNICAL CHARACTERISTICS:

The filter has the following technical specifications:

Filter efficiency*	>99.9% BFE >99.9% VFE
Weight	17 grams
Pressure Drop (Resistance to Flow)	<3 cmH_2O @ 60 LPM
Compressible Volume (Dead Space)	25 ml (Nominal)
Connections	Barbed fitting, Patient end for connection to corrugated tubing 22 mm I.D., Patient end

* Tested per Mil-M-36954C, particle challenge range 0.3 to 10μ using Staphylococcus aureus bacteria (mean particle size 1μ) and using Bacteriophage PHI X 174 virus (mean particle size 0.027μ).

NON-CLINICAL DATA:

Performance and specifications of the filter meet the requirements of the following standards:

ISO 5356-1; Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets.
ISO 9360; Anaesthetic and respiratory equipment – Heat and moisture exchangers for humidifying respired gases in humans, as it pertains to resistance to flow, compressible volume, and leakage.

In addition, data submitted demonstrates that the device meets all technical specifications listed in the above paragraph.

CONCLUSION:

The comparison to the predicate device demonstrates that the modified device is safe and effective and is substantially equivalent to the predicate device.

Very truly yours,

SIMS PORTEX INC.

Timothy J. Talcott
Director, Regulatory Compliance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 5 2001

Mr. Timothy J. Talcott
Sims Portex, Inc.
10 Bowman Drive
P.O. Box 0724
Keene, NH 03431

Re: K002506
Sims Portex Breathing Filter
Regulation Number: 868.5260
Regulatory Class: II (two)
Product Code: 73 CAH

Dear Mr. Talcott:

This letter corrects our substantially equivalent letter of December 14, 2000, regarding the Sims Portex Breathing Filter. Our letter identified the product code as 73 CAT. This is in error; the correct product code is 73 CAH as indicated above.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to continue marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B: INTENDED USE OF DEVICE

PROPOSED INDICATIONS FOR USE:

510(k) Number (if known): Unknown K002506

Device Name: Breathing Filter for Disposable Anesthesia Breathing Circuits

Indications For Use:

To be used with adult anesthesia breathing circuits where filtration of inspired and/or expired gases is required.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

Division of Cardiovascular & Respiratory Devices
510(k) Number K002506

3